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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/411,797 10/01/99 HERWECK

S ATA-257

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

QM12/0620

EXAMINER

L.A.M.A.	
ART UNIT	PAPER NUMBER

3763
DATE MAILED:

5
06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/411,797	Applicant(s) HERWECK ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 44-52 is/are pending in the application.
 4a) Of the above claim(s) 28-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 44-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

During a telephone conversation with David Lane on June 12, 2001 a provisional election was made to prosecute the invention of the device, claims 1-27 and 44-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6-20, 24-27 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al., 5,336,178.

Kaplan discloses a member (28 and 32) constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils; the member being deployable from a first, reduced diameter configuration to a

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second, increased diameter configuration, wherein the wall of the member includes at least one microporous portion (32) having a porosity sufficient for a fluid to permeate through the wall, spaces between the nodes substantially controlling the permeation of fluid through the wall. The area between the orifices (34) constitute the nodes.

Moreover, the nodes are oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall.

The nodes are considered to be oriented substantially perpendicular to the longitudinal axis of the member.

The micro-channels (34) within the microporous portion of the wall are sized to permit the fluid to pass from the inner surface to the outer surface of the wall.

The size of the micro-channels varies longitudinally, and circumferentially, see column 8, lines 31-46.

The member has a unitary construction of generally homogenous material.
The fluid includes a medicinal agent.

The medicinal agent may be thrombolytics, see column 1, line 34.

The microporous portion of the wall borders a second portion of the wall that is generally impermeable to the pressurized fluid, see Figure 1A. Member (28) constitute a second portion of the wall that is generally impermeable.

As to claim 11, it is inherent that the member deploys to the second configuration upon application of a fluid having a pressure of approximately 1 psi to 250 psi.

As to claim 12, it is inherent that the porosity is sufficient to allow fluid to pass therethrough at a flow rate of approximately 0.01 ml/min to 100 ml/min.

see col 7
line 36-37

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As to claims 17, 19 and 20, the wall further includes a second microporous portion having a porosity sufficient for the fluid to permeate through the wall, see column 8, line 20. A second conduit (32) can constitute the second microporous portion.

As to claim 18, an impermeable portion of the wall (28) is interposed between the microporous portion and the second microporous portion.

As to claim 24, the microporous portion is considered to have a hydraulic conductivity less than the hydraulic conductivity of the body vessel.

As to claims 25-27 and 44, the member is considered to be constructed of a biocompatible fluoropolymer material, see column 12, line 45.

Claims 1-4, 6-10, 13-20, 24-27 and 44-49 are rejected under 35 U.S.C. 102(b) as
being anticipated by Butler et al., 5,843,069.

Butler discloses a first layer and a second layer of biocompatible material, see column 8, line 66 – column 9, line 5, having a microstructure of nodes interconnected by fibrils, the second layer overlying the first layer, the wall of the fluid delivery device extending between an inner surface of the first layer and an outer surface of the second layer, wherein the wall of the fluid delivery device includes at least one microporous portion, substantially all of the nodes within the microporous portion being oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface of the first layer to the outer surface of the second layer, the micro-channels being sized to permit fluid to permeate from the inner surface of the first layer to the outer surface of the second layer.

*Butler
in expanded*

Moreover, Butler discloses PTFE material at column 4, line 21, and a fluoropolymer material, see column 14, line 5.

The micro-channels of the first layer are considered to be sized differently than the second layer, since the layers may be made of different materials and have different permeability, see column 8, see line 58 – column 9, line 5.

Specifically as to claim 48, the internodal distances in the first layer are considered to be different from the internodal distance in the second layer, since the layers may be made of different materials and have different permeability, see column 8, see line 58 – column 9, line 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 21-23, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al., 5,843,069.

Butler discloses the invention substantially as claimed, see above. However, Butler does not disclose the specific internodal distance, nor the hydraulic conductivity as claimed.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a material and permeability as desired for a particular

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medical application, as taught by Butler, see column 8, lines 58-65, which encompasses materials having an internodal distance or hydraulic conductivity as claimed by Applicant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sahatjian, 5,533,516, discloses a balloon catheter having a porous membrane.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.

June 16, 2001




ANH TUAN T. NGUYEN
PRIMARY EXAMINER

6/12/01

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.